PART C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter

Alliance Medical Corporation
10232 51st Street
Phoenix, Arizona 85044

2. Contact Person

Don Selvey
Vice President, Regulatory Affairs & Quality Assurance
Alliance Medical Corporation
(480) 763-5300 – Telephone
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dselvey@reprocessing.com

3. Device Name

a. Trade or Proprietary Name

Electrophysiology Catheter

b. Common Name, Usual or Classification Name

Electrode recording catheter

4. Predicate Devices

Bard	Cordis Webster*	Daig**	EP Technologies	Medtronic
K891908	K892265	K914278	K913375	K931794
K904080	K953663	K942379	K924108	K951347
K912213	K953678	K002976	K924109	K953185
K921872	K955817		K924163	K964272
K971265	K991531		K940167	K981642
	K992965		K940168	
	K002333		K003452	

*The Celsius/CelsiusII diagnostic catheters were approved under PMA P950005.
**The Livewire diagnostic catheter was approved under PMA P960016.

5. Description of the Device

Diagnostic Electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation.

EP catheter designs all incorporate a connector, a handpiece, a flexible polymeric shaft, and a distal tip containing two or more electrodes. The distal tips of steerable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

6. Intended Use of the Device

Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiological mapping of cardiac structures.

7. Comparison of the Technological Features of the Reprocessed and Original Devices

Diagnostic catheters are available in various configurations. Key parameters include the size of the tip, number of electrodes, length, curve of the tip, and whether or not the tip is deflectable. Since reprocessing does not significantly change any of these parameters, the reprocessed catheters are the same as the original devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Alliance Medical Corporation
c/o Mr. Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
10232 South 51st Street
Phoenix, AZ 85044

Re: K012708
Trade Name: Reprocessed Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: August 9, 2002
Received: August 12, 2002

Dear Mr. Selvey:

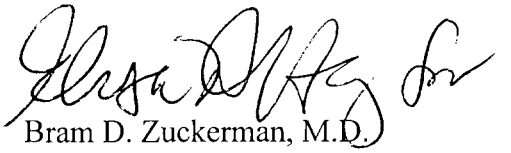
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number: K012708
(if known)

Device Name: Electrophysiology (EP) Catheter

Sponsor Name: Alliance Medical Corporation

Indications for Use:

Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiological mapping of cardiac structures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012708
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Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)